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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,151

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David K. Swanson

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EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

10/13/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,151	<b>Applicant(s)</b> SWANSON, DAVID K.	
	<b>Examiner</b> AARON ROANE	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14, 17, 19, 20, 32-34, 36-38, 40-42, 45, 48 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 17, 19, 20, 32-34, 36, 37, 40-42, 45, 48, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) 52 and 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/14/2010 has been entered.

***Claim Rejections - 35 USC § 112***

Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the limitation "the flexible carrier" in line 2. There is insufficient antecedent basis for this limitation in the claim.

In order to provide an initial examination and search, the examiner interprets claim 53 as depend on claim 34.

**Invocation of 112, sixth paragraph**

Claim 32 recites in lines 6-9 "means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure,"

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which is interpreted by the examiner as Applicant invoking 112, sixth paragraph. The examiner equates the means for securing as equivalent to the anchor of claim 33.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17, 19, 20, 32-34, 36, 37, 40-42 and 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (U.S. Patent 4,144,890) in view of Edwards et al. (U.S. Patent 5,398,683).

Regarding claims 14, 17, 32-34, 36, 37, 40-42 and 45-51, Hess discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode (“small flat disk electrode”, see col. 3:36-52 and figure 7) configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and an anchor or means for securing (collectively portions defined by 25, 27, 31, 33 and 37 in col. 2:42-55 and figures 1-3 or portions defined by 41-44 in col. 3:9-18 and figures 4-6), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by

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piercing the tissue and pressing the stimulation element against the tissue, see col. 2:12-col. 3:52 in general. Hess further disclose “[o]ne type of electrode which may be used is formed by allowing half turns of the helically-coiled conductor to project through the bottom face of the insulating base as illustrated at 53 in FIG. 7. In some cases, a small flat disk electrode resting against the tissue to be stimulated may also be entirely sufficient,” see col. 3:36-52 and figure 7. Hess is silent as to the diameter of the “small flat disk electrode.” Hess also fails to disclose a second tissue stimulation element.

**Although Hess discloses a first stimulation element, Hess fails to disclose a second stimulation element.** Edwards et al. disclose a medical catheter device and teach providing the catheter with “two pacing electrodes 75 are 0.035" platinum dot electrodes, and are positioned substantially diametrically opposite each other” (0.035" is 0.889 mm) in order to provide pacing/stimulating electrical energy to tissue, see col. 8:21-25 and figure 8. **It is extremely well known in the electrosurgical/electrotherapeutic art alternate use of a monopolar electrode configuration and a configuration of bipolar electrodes. Some of the extremely well known advantages of the configuration of bipolar electrodes over that of the monopolar electrode configuration are a) limitation of energy conduction to a more defined and smaller area, b) less wasted energy and c) no need for external return electrode pads.** Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Edwards et al., to use two small disk like electrode of about 0.889 mm in size that are positioned diametrically opposite each other on the device in order to provide pacing/stimulating electrical energy to tissue, **and further as is**

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**extremely well known in the art, to provide the device with relatively closely spaced first and second stimulation elements/electrodes in order to provide advantages over the monopolar configuration, the advantages being a) limitation of energy conduction to a more defined and smaller area, b) less wasted energy and c) no need for external return electrode pads.**

Regarding claims 19 and 20, Hess discloses that the anchor comprises a flexible carrier (elongated element defined by ends 42 and 42) that is non-linear when in the relaxed state, as it has a u-shaped or cup shaped transverse cross-section, see col. 3:9-18 and figures 4-7.

#### ***Allowable Subject Matter***

Claims 52 and 53 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Reasons for Allowance***

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not disclose, imply, suggest, teach and/or provide a properly motivated combination thereof disclosing the claimed invention as defined by claims 52 and 53, wherein

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particular attention is given to the location of the first and second stimulation elements with respect to the first location (where the tissue is pierced by the central carrier).

### ***Response to Arguments***

Applicant's arguments with respect to claims 14, 17, 19, 20, 32-34, 36, 37, 40-42 and 45-51 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Due to Applicant's amendment citing a second stimulation element/electrode, the examiner provided rationale disclosing the advantages of bipolar operation over monopolar operation, which is extremely well known to one of ordinary skill in the art.

As a courtesy to Applicant and in the hopes of expediting prosecution, the examiner would like to make a few comments. Applicant may wish to further limit the independent claim with structural features as the elected embodiment is clearly distinct from the devices of Hess. However, these distinctions need to be positively recited in the claims. In particular, Applicant might wish to recite the pairs of 704 and 708, their criss-cross engagement and how they relate to some of the other positively recited structural features.

**The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.**

**Due to the RCE, this action is made non final.**

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/  
Examiner, Art Unit 3769